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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,116	02/27/2002	Nicolas Glaichenhaus	1721-47	6350

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/048,116	GLAICHENHAUS ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 1/28/02, 12/6/04 & 4/11/05.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) 1-3 and 7-11 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 4-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/27/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 1/28/02 and Applicant's responses filed 12/6/04 and 4/11/05 are acknowledged and have been entered.

2. Applicant's election of Group II (claims 4-6), and species of "cDNA construct of Example 1 which is also provided in Figure 1 providing the cDNA sequence from position 420 to 1940 as well as the coated peptide" in Applicant's responses 12/6/04 and 4/11/05, respectively, is acknowledged.

However, it is noted by the Examiner that the cDNA sequence in Figure 1 or Example 1 is SEQ ID NO: 1, however, there are not 1940 nucleic acid bases in SEQ ID NO: 1. The specification on page 10 discloses that the cDNA construct coding for the IAα^d/Fc recombinant protein "is illustrated in Figure 1 which gives the cDNA sequence, from position 420 to 1940, and that of the coded peptide (437-1921) (SEQ ID NO: 1)".

The Examiner has searched SEQ ID NO: 1. Upon consideration of the prior art, the Examiner has extended the search to include additional species. Claims 4-6 are currently being examined as they read on a nucleotide sequence having a reading frame corresponding to all or part of a soluble recombinant class II MHC $\alpha\beta$ dimer or class I heavy chain/β2m dimer, said dimer comprising all or part of an Fc region at the carboxy terminus of one or both chains, and optionally leucine zippers, complexed in multimers and complexed with other proteins and comprising several binding sites for the constant regions of immunoglobulins, expression vector and host cell thereof.

Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Accordingly, claims 1-3 and 7-11 (non-elected Groups I, III and IV) are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

3. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

The abstract discloses "a dimer which is itself formed by +/- and ^{2} molecule chains". This disclosure does not appear to describe the claimed invention.

4. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

6. Applicant is required under 37 C.F.R. 1.821(d) to amend the specification to list the appropriate SEQ ID NOS for sequences disclosed in the specification (for example, in the brief description of the drawings for Figures 1 and 3).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

a. Claim 4 is indefinite in the recitation of "Nucleotide sequence having a reading frame corresponding to all or part of a protein according to claim 1" because it is not clear what is meant, i.e., what the metes and bounds of the claim are. It is not clear what is meant because claim 1 recites "Soluble recombinant proteins, constituted as a minimum from a dimer that is itself formed from α and β chains of class I or class II MHC molecules...these chains comprising if necessary leucine zippers, characterized in that they are combined in several dimers and in particular in tetramers or in octamers and are complexed with natural or artificial protein, comprising several binding sites for the constant regions of the immunoglobulins...".

b. Claim 5 is indefinite in the recitation of "in particular plasmids, characterized in that they have a sequence according to claim 4" because it is not clear what the metes and bounds of the claim are, i.e., "in particular plasmids", and "characterized in that they have a sequence according to claim 4", the latter limitation as enunciated in part "a" supra.

c. Claim 4 is indefinite for depending upon non-elected claim 1. Applicant is required to rewrite said claim in independent form

9. For the purpose of prior art rejections, the filing date of the instant claims 4-6 is deemed to be the filing date of PCT/FR00/02193, i.e. 7/28/00, as an English language translation has not been provided for the foreign priority document FR 99/09862.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/09064 A1 (Applicant's IDS reference).

WO 99/09064 A1 teaches nucleic acid molecules encoding the chains of dimers or tetramers, said dimers or tetramers comprised of dimers of MHC class II α chain extracellular regions fused at the carboxy-terminus, including via linker sequence, to Ig hinge, CH2, CH3 regions plus MHC class II β chain extracellular regions fused including via linker sequence to Ig hinge, CH2, CH3 regions, i.e., nucleic acid molecules encoding *a part* of a protein according to instant claim 1. In addition, WO 99/09064 A1 teaches that the nucleic acid sequences of the individual chains may also include the sequence of an antigenic peptide. WO 99/09064 A1 teaches expression vectors, including plasmid vectors (vectors with "p" as the first designation), and prokaryotic or eukaryotic host cells comprising the vector and nucleic acid sequence of the MHC class II chain(s) (see entire document, especially abstract, summary of the invention, detailed description of the invention at pages 6-11 through the first full paragraph, page 13 at line 15 through page 14 at line 17 and page 19 at lines 13-18, claims).

12. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/03552 A2 (Applicant's IDS reference).

WO 98/03552 A2 teaches nucleic acid molecules encoding the chains of dimers or multimers, said dimers or multimers comprised of dimers of MHC class II α chain extracellular regions fused at the carboxy-terminus, including via linker sequence to Ig hinge, CH2, CH3 regions plus MHC class II β chain extracellular regions fused, including via linker sequence, to Ig hinge, CH2, CH3 regions, and additionally comprising nucleic acid sequence encoding leucine zippers, i.e., nucleic acid molecules encoding *a part* of a protein according to instant claim 1. In addition, WO 98/03552 A2 teaches that the nucleic acid sequences of the individual chains may also include the sequence of an antigenic peptide. WO 98/03552 A2 teaches expression vectors such as pCMV4. WO 98/03552 A2 also teaches nucleic acid molecules/expression vectors/host cells thereof, encoding dimers of class I MHC comprising class I MHC extracellular domains, linkers and β2m (such as plasmid pHuActβ2), and prokaryotic host cells (such as *E. coli*) comprising the vector and nucleic acid sequence of the MHC

class II chain(s) (see entire document, especially abstract, page 2 at lines 20-35, page 3 at lines 1-35, page 4 at lines 1-36, page 6 at line 1 through page 8 and claims).

13. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/10220 A1 (Applicant's IDS reference).

WO 93/10220 A1 teaches nucleic acid molecules encoding the chains of dimers, said dimers comprised of MHC class II α chain extracellular regions fused at the carboxy-terminus, including via linker sequence, to Ig hinge, CH2, CH3 regions plus MHC class II β chain extracellular regions fused including via linker sequence to Ig hinge, CH2, CH3 regions, i.e., nucleic acid molecules encoding *a part* of a protein according to instant claim 1. WO 93/10220 A1 teaches expression vectors, including plasmid vectors, and prokaryotic or eukaryotic host cells comprising the vector and nucleic acid sequence of the MHC class II chain(s) (see entire document, especially abstract, page 3 at lines 1-32, page 4 at lines 1-25, page 7 at lines 15-29, page 8 at lines 30-32, page 9 at lines 23-30, page 10 through page 11 at line 24 and lines 1-37, page 12 at lines 1-11, page 17 at line 20 through page 20 at line 19, claims, figures).

14. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/06749 A2 (Applicant's IDS reference).

WO 98/06749 A2 teaches nucleic acid molecules encoding the chains of dimers or multimers, said dimers or multimers comprised of MHC class II α chain extracellular regions fused at the carboxy-terminus, including via linker sequence, to Ig Fc region or portions thereof, plus MHC class II β chain extracellular regions fused including via linker sequence to Ig Fc region, i.e., nucleic acid molecules encoding *a part* of a protein according to instant claim 1. WO 98/06749 A2 teaches expression vectors, including plasmid vectors, and prokaryotic or eukaryotic host cells comprising the vector and nucleic acid sequence of the MHC class II chain(s) (see entire document, especially abstract, pages 4 through 7 at line 9, brief description of the drawings for Figures 1-4, Figures 1-4, pages 15 through 19 at line 76, page 30 at lines 1-11, page 39 at lines 13-32 through page 40 at line 23, page 42 at lines 26-31, page 44 at lines 1-5, page 47 at lines 3-8, claims).

15. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/28191 A1 (Applicant's IDS reference).

WO 97/28191 A1 teaches nucleic acid molecules encoding MHC class II molecules complexed with the Fc region of an Ig heavy chain, .e., nucleic acid molecules encoding *a part* of a protein according to instant claim 1, expression vectors, including plasmids, comprising the said nucleic acid molecules, and eukaryotic host cells thereof. WO 97/28191 A1 further teaches that the MHC/Ig proteins produced from the said nucleic acid molecules are complexed with protein A or G, as is the soluble recombinant protein of instant claim 1 (especially Example 2 on pages 49-55).

16. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Cullen et al (Cell. Immunol. 192 : 54-62, 2/25/99).

Cullen et al teach an MHC class I IgG1 Fc region (i.e., CH2 and CH3 domains of IG1) fusion protein, nucleic acid molecule encoding the said fusion protein, i.e., *a part* of a protein according to claim 1, and plasmid expression vector and host cell comprising said nucleic acid molecule/vector. Cullen et al further teach complexing the fusion protein with protein A, i.e., multimerizing the protein. Cullen et al further teach that valency can also be increased using an IgM Fc moiety (see entire article, especially abstract, page 55 column 1 at the second full paragraph, materials and methods on page 55, results on page 56 at column 2, page 57 through the paragraph spanning columns 1 and 2, page 61 column 1).

17. The Cullen et al reference in Applicant's IDS Form 1449 filed 2/27/02 has been crossed out because Applicant provided only an abstract and the Examiner has cited the Cullen et al reference in it's entirety in the instant rejection and on the accompanying form 892.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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